COLLEGE of AMERICAN PATHOLOGISTS

August 27, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE. SARS-CoV-2 Nucleic Acid Test (NAT) Medicare Contractor Pricing

Dear Administrator Verma:

The College of American Pathologists (CAP) requests that the Centers for Medicare and Medicaid Services (CMS) have all Medicare Administrative Contractors (MACs) immediately reconsider their SARS-CoV-2 nucleic acid test (NAT) pricing effective May 19, 2020, and that, in lieu of another MAC led-process, the CMS should issue a special ruling to increase SARS-CoV-2 NAT CLFS payment rates at the national level. The CAP recommends that the CMS, in a parallel process, delete HCPCS codes U0001, U0002, U0003, and U0004 and utilize the new CPT code 87635 to support administrative simplification and burden reduction, and more accurately adopt a uniform, single payment rate for all SARS-CoV-2 nucleic acid tests. Current FDA EUA approved NAT *in vitro* diagnostics all employ viral nucleic acid amplification in the detection process, regardless of specific methodology and test throughput. We believe the Medicare CLFS payment rates established for SARS-CoV-2 nucleic acid testing are valued too low, and that the established processes for determining these clinical laboratory test prices were not appropriately followed. The prices established by the MACs failed to account for costs and resources necessary to bring testing online during the national public health crisis for laboratories of all sizes and localities.

The current CMS MAC payment amount for CPT code 87635 should adequately reflect the clinical labor, equipment, reagents and supplies necessary to perform all SARS-CoV-2 NAT diagnostic assay in the typical laboratory setting, and not be differentiated on basis of methodology or type of analytical platforms used [which tends to preferentially favor the large, high volume testing providers]. It remains unfathomable that such low payment rates could be established for this crucial testing—and, in a way that has economically disadvantaged so many primary testing providers in the acute care hospital and academic laboratory settings who are responsible for rapidly identifying and caring for COVID-19 patients in the midst of this pandemic. In fact, a majority of these frontline providers have been forced to diversify and develop more than one (and often multiple) NAT methods and are now managing various different combinations of analytical platforms, to help address the unprecedented shortages and unmet demands for expanded and more accessible SARS-CoV-2 testing in their local communities. We are greatly concerned that all provider laboratories cannot sustain these underpayments indefinitely, along with the other overall increased costs associated with doing business during the national public health emergency. **At a minimum, all SARS-CoV-2 NAT Medicare CLFS payment rates should currently reflect a national payment rate equivalent to the high-throughput test HCPCS codes (U0003 and U0004), based on the information we have received to date from a diverse cross-section of clinical laboratory providers. We believe that CMS should also make the increased pricing update for CPT code 87635 retroactive to beginning from the date that CPT code was created and implemented, March 16, 2020**.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP understands the complexities and evolution of the COVID-19 pandemic and related SARS-CoV-2 nucleic acid testing. The created HCPCS codes served as important steps to support the immediate need for testing. Unfortunately, as the pandemic has evolved, the ongoing need for this testing has been exacerbated by the need to decrease the time from specimen procurement to test result notification (a.k.a., turnaround time), so that patients can be quickly identified, quarantined, and begun on an appropriate treatment regimen. In many circumstances, the only way to accomplish this is by decentralizing the testing from remote, national/regional commercial laboratories to local hospital and clinic laboratories, including point-of-care methodologies. By their very nature, time-sensitive testing for the diagnosis and management of symptomatic individuals with COVID-19—as well as minimizing asymptomatic SARS-CoV-2 infection/exposure risks in the delivery of other health care (e.g., surgery, invasive procedures)—at these sites will not always be “high throughput” and will typically have a higher (not a lower) cost per test. However, they provide an essential (timely) result for the treating clinician to make key medical decisions at the frontline. Unfortunately, the current HCPCS NAT coding paradigm does not adequately recognize these important contributions and the full cost burden of providing testing across the continuum of all laboratory settings.

CMS Should Delete HCPCS U Codes and Utilize CPT Code 87635
The CAP urges the CMS to delete HCPCS codes U0001, U0002, U0003, and U0004 and utilize the new CPT code 87635 to accurately report and price laboratory tests for SARS-CoV-2 nucleic acid detection. We believe the HCPCS codes are unnecessary present significant financial barriers and confusion among providers, who must utilize whichever testing modality will provide urgently needed results rather than selecting among modalities that are often only theoretically available due to lack of critical supplies. CPT code 87635 accurately and succinctly describes the tests being performed and there is neither need nor benefit to subdividing the test descriptions.

CMS Payment Rates are Inadequate to Cover Test Costs
The CMS announced approximated payment rates of about $36 for Centers for Disease Control and Prevention (CDC) developed coronavirus (SARS-CoV-2) NAT procedures, approximately $51 for laboratories performing non-CDC tests, and $100 for tests making use of high throughput technologies - these payment rates cause great concern and confusion amongst providers.

Based on our review of costs from our members providing or seeking to offer these tests in their laboratory, a SARS-CoV-2/COVID-19 survey of directors of CAP accredited laboratories, a study of hospital charges across the country, and in depth interviews with laboratory cost managers, **it is clear that the lower payment amounts set for these tests by the CMS are woefully inadequate to cover the costs in the typical laboratory performing SARS-CoV-2 nucleic acid testing.**

The payment rates were set without access to costs and charges for the test, and the MACs have not provided any methodology used to establish their rates. The cost of the reagents, supplies, and clinical labor involved to provide one of these tests, as well as the incremental equipment and other fixed capital costs, far exceed the current MAC reported payment amounts.

All of the laboratory cost managers we interviewed indicated their laboratory must utilize multiple testing platforms as they struggle to keep up with test demand. The multiple platforms are necessary as typically no single vendor can reliably supply testing reagents and other supplies, and thus provide the necessary flexibility to deal with the continuously erratic supply chain. As one testing platform runs low or out of supplies, others are brought online until needed supplies are obtained. It

is not atypical for laboratories to be forced to utilize a combination of high and low throughput platforms in order to address the clinical need. Additionally, as laboratories develop and maintain multiple testing platforms to keep up with the demand for SARS-CoV-2 tests, they purchase new equipment, set up the equipment, develop protocols, proficiency test, initiate supply chains, train clinical staff, run tests, and maintain the equipment. Laboratory cost managers also report that when there is insufficient testing capability, they also send the tests out to large laboratories, adding an additional layer of costs and delayed results. Significant costs are being incurred across the country as laboratories struggle with this crisis. All laboratories reported that they will report significant losses and do not anticipate making them up.

Inadequate pricing for SARS-CoV-2 NAT procedures will severely limit the number of laboratories that would be willing to continue offer these tests and will adversely impact national/local efforts to increase testing capacity and improve access to testing. If this situation is not addressed quickly, this will only exacerbate testing delays and further complicate the current crisis. In the current scenario, large, medium, and small hospital laboratories are all necessarily involved in providing these tests. In fact, our recent survey found that medium-sized hospital labs account for 2/3 of labs providing SARS-CoV-2 nucleic acid testing.

From our survey, only 30% of independent labs and 38% of reference labs reported providing SARS-CoV-2/COVID-19 related testing. Academic and non-academic hospitals together accounted for 80% of the labs providing this testing; 74% of labs based in academic hospitals and 70% of labs based in non-academic hospitals are currently offering SARS-CoV-2 nucleic acid detection tests. Large independent and reference laboratories have significantly different cost structures (lower costs) than do most hospital laboratories; the basis for this cost efficiency is batch testing volume, and the price paid by the community for this cost efficiency is long turnaround time and consequent diminished clinical utility of the results. The CAP believes that the cost structures of the typical laboratory performing SARS-CoV-2 testing should be taken into account when these prices are determined and the only way to address inadequate testing levels will be to establish prices that cover the costs of these tests where they are both typically and most effectively being provided.

Commercial payers, seeking to set appropriate pricing, typically refer to MAC pricing as a benchmark for their own fee schedules. The CAP recently submitted its recommendation to the CMS for the Clinical Laboratory Fee Schedule for its Annual Laboratory Public meeting June 22, 2020, for calendar year 2021 pricing of CPT code 87635. Our recommendation is for a cross-walked price of $95.80 for CPT code 87635 as shown below: Crosswalk to 87502 *Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types as comparable resources are required to complete the assay*. Inappropriate pricing hinders the progress of controlling this virus. The current CMS MAC payment amount for CPT code 87635 does not adequately reflect the clinical labor, equipment, reagents, and supplies necessary to perform this SARS-CoV-2 diagnostic assay in the typical laboratory setting. **The CAP urges the CMS to immediately (ahead of calendar year 2021) to establish increased SARS-CoV-2 test pricing for CPT code 87635.**

MAC Process for Developing Payment

The CAP is concerned with the lack of transparency and full disclosure associated with the SARS-CoV-2 test prices established by the MACs. According to the CMS, MAC-specific amounts are supposed to be established using the following sources of information, if available: (1) charges for the test and routine discounts to charges, (2) resources required to perform the test, (3) payment amounts determined by other payers, (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant, and (5) other criteria that CMS determines appropriate. While the CMS first published prices from each of the MACs on March 12, 2020, and

again on May 19, 2020, the uniformity of pricing proposed starkly illustrates the problems inherent in gapfill methodology for an emergent and novel test. It is unclear how each MAC determined the same exact price, or whether the MACs independently established and submitted their own gapfill pricing information or simply adopted another MAC's pricing. Most importantly, what data was utilized for each code? This opaque process and resultant pricing clearly will have many adverse and unintended consequences to providers, patients, health care institutions and the public, that will limit access to these medically necessary services. For the MACs to develop such similar prices indicates the MAC process did not take into account critical data and information received from laboratories regarding necessary supplies, clinical labor and equipment, critical to providing SARS-CoV-2 tests to address the demands of the public health care crisis.

These and other factors leave us concerned that laboratories that have been providing these tests at a loss may not be able to continue to offer these services. Furthermore, because Medicaid and commercial payers often use Medicare as a benchmark when developing their own payment policies, the inappropriate pricing established at the MAC level could influence payment rates set by other payers. In some states, Medicaid state programs are set at a percentage of the Medicare rates, including those listed on the Clinical Laboratory Fee Schedule. As a result, access to these services may be further restricted.

The cost to the healthcare system to deal with a pandemic like SARS-CoV-2 is unprecedented and unknown. **The CAP urges the CMS and all MACs immediately establish increased SARS-CoV-2 test pricing for CPT code 87635.**

The CAP requests that the CMS withdraw HCPCS codes U0001, U0002, U0003, and U0004 and establish a new price for CPT code 87635 that ensures that laboratories are reimbursed appropriately for the resources needed to perform the tests.

The College of American Pathologists appreciates your consideration of these comments. Please direct questions to Pam Wright at pawrigh@cap.org or Todd Klemp at tklemp@cap.org.

Sincerely,

Jonathan L Myles, MD, FCAP
College of American Pathologists
Board of Governors
Chair, Council on Government and Professional Affairs